IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN THE APPLICATION OF: Michael R. Harter et al	GROUP: 3626
U. S. SERIAL NO: 10/813,421	EXAMINER: Nguyen, Tran N.
FILING DATE: March 30, 2004	Atty. Doc. No: TBM

TITLE: Method for Identifying Allergens and Other Influencing Agents That may Cause a Reaction

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_____   4/28/2008

Robert J. Harter – Reg. 32,031   date

La Crosse, Wisconsin

April 28, 2008

Reply Brief Under 37 CFR 41.41

Commissioner for Patents

Alexandria, VA 22313-1450

This reply brief under 37 CFR 41.41 is in response to the Examiner's Answer mailed on March 20, 2008.

This reply brief is being submitted along with a Request for Oral Hearing Before the Board of Patent Appeals and Interferences.

(i) Real Party in Interest

Michael R. Harter, Robert J. Harter, and Tyler R. Harter are co-inventors that comprise the real party in interest.

(ii) Related Appeals and Interferences

None

(iii) Status of Claims

Claims 1 and 3 – 33 currently stand rejected, and the rejection of these claims is being appealed.

Claim 2 was canceled on March 1, 2007, thus claim 2 is not being appealed.

(iv) Status of Amendments

No amendments were filed after the final rejection

(v) Summary of Claimed Subject Matter

Independent claim 1 covers the concept of identifying, for example, a person's food allergies by computing a correlation value for every food the person consumes over several days or weeks and any reactions the person experiences. By evaluating the resulting computations, the method can identify allergens without a skin prick test and without the person having to follow an elimination diet or any other particular diet (see Abstract of the Disclosure).

Claim 1 specifically recites, "computing a plurality of correlations corresponding to the plurality of possible influencing agents as each of the plurality of possible influencing agents relate to the reaction; and based on the plurality of correlations, determining and displaying the suspect influencing agent."

More specifically, independent claim 1 finds support in the specification and/or drawings as follows:

1.　　A method of using a computer and a computer display for identifying a suspect influencing agent that may be causing a reaction in an individual, wherein the suspect influencing agent is one of a plurality of possible influencing agents, the method comprising:

displaying the plurality of possible influencing agents on the computer display (Fig. 1, item 28 and pg. 7, line 22);

displaying the reaction on the computer display (Fig. 1 item 30 and pg. 7, lines 23 and 24);

for a first period, selecting a first plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the first plurality of influencing agents during the first period, wherein the step of selecting the first plurality of influencing agents is via the computer (Fig. 1, item 36 and pg. 7 line 26 – pg. 8 line 7);

for a second period following the first period, selecting a second plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the second plurality of influencing agents during the second period, wherein the step of selecting the second plurality of influencing agents is via the computer (Fig. 2, item 40 and pg. 8, line 8 – 17);

selecting, via the computer, the reaction that the individual experienced during at least one of the first period, the second period, and a third period, wherein the third period follows the second period (Fig. 2, item 48; Fig. 3, items 58 and 62; and pg. 8, lines 17 – 23);

computing a plurality of correlations corresponding to the plurality of possible influencing agents as each of the plurality of possible influencing agents relate to the reaction (pg. 9, lines 15 – 17; pg. 9, lines 23 – 25; and pg. 10, lines 6 – 10); and

based on the plurality of correlations, determining and displaying the suspect influencing agent (Fig. 4 items 68 and 72 and pg. 9, line 18 – pg. 10 line 2).

Dependent claim 3 covers the concept of identifying the allergen by sorting, for example, food items based on their correlation values (Fig. 4, items 72 and 84).

Dependent claim 4 covers the concept adding, for example, additional food items after the study period has already been started (pg. 8, lines 5 – 7).

Dependent claim 5 covers the concept of entering, for example, food items by simply mouse-clicking on them rather than having to retype them in every time (pg. 8, lines 9 – 12).

Dependent claim 6 covers the concept of selecting reactions by simply mouse-clicking on them rather than having to retype them in every time (pg. 8, lines 15 – 16).

Dependent claim 7 covers the concept of a user being able to enter their own reactions rather than using only those preloaded in the software program (pg. 7, lines 21 – 22.

Dependent claim 8 covers the concept of single-screen viewing of, for example, reactions and food items, which makes it easier to select those items (see Figs. 1 or 2).

Dependent claim 9 covers the concept of helping recognize an allergen by way of a graphical display (Fig. 6).

Dependent claim 10 covers the concept of rating a reaction's magnitude, such as severe, mild or average (pg. 9, lines 4 – 6).

Dependent claim 11 covers the concept of rating the magnitude of an influencing agent. A food consumed on a particular day, for example, might be assign as being a large, medium or small serving portion (pg. 11, line 20; and Fig. 6, item 94).

Dependent claim 12 covers the concept of using the correlation value as an indicator of the likelihood of a future reaction.

Dependent claim 13 covers the concept of disregarding data collected during a woman's menstrual period.

Dependent claim 14 covers the concept of a food item being the possible influencing agent (pg. 6, line 28 – pg. 7 line 16).

Dependent claim 15 covers the concept of an influencing agent being an ingredient of another influencing agent (pg. 11, lines 23 – 25).

Dependent claim 16 covers the concept of delayed reactions (pg. 10, line 16 – 18).

Dependent claim 17 covers the concept of "confidence values" that indicates the reliability or relevance of a correlation value (pg. 10, lines 8 and 9).

Dependent claim 18 covers the concepts of a daily log.

Dependent claim 19 covers the concept of the influencing agent being an allergen (pg. 2, line 5).

Dependent claim 20 covers the concept of the influencing agent being an environmental exposure (pg. 6, line 28 – pg. 7 line 16).

Dependent claim 21 covers the concept of the reaction being physical pain (pg. 6, line 28 – pg. 7 line 16).

Dependent claim 22 covers the concept of the reaction being respiratory-related (pg. 6, line 28 – pg. 7 line 16).

Dependent claim 23 covers the concept of the reaction is skin related (pg. 6, line 28 – pg. 7 line 16).

Dependent claim 24 covers the concept of the reaction pertains to blood pressure (pg. 6, line 28 – pg. 7 line 16).

Dependent claim 25 covers the concept of the reaction is fatique (pg. 6, line 28 – pg. 7 line 16).

Dependent claim 26 covers the concept of the reaction is mentally-related (pg. 6, line 28 – pg. 7 line 16).

Dependent claim 27 covers the concept of the reaction being a seizure (pg. 6, line 28 – pg. 7 line 16).

Dependent claim 28 covers the concept of the reaction being an emotional disturbance (pg. 6, line 28 – pg. 7 line 16).

Dependent claim 29 covers the concept of the influencing agent pertains to an activity (pg. 6, line 28 – pg. 7 line 16).

Dependent claim 30 covers the concept of the influencing agent pertains to an individual's amount of sleep (pg. 6, line 28 – pg. 7 line 16).

Dependent claim 31 pertains to the influencing agent being accessed via the Internet (pg. 4, lines 21 and 22).

Independent claim 32 is a combination of claims 1, 4 and 5. More specifically, independent claim 32 finds support in the specification and/or drawings as follows:

32.   A method of using a computer and a computer display for identifying a suspect influencing agent that may be causing a reaction in an individual, wherein the suspect influencing agent is one of a plurality of influencing agents, the method comprising:

entering into the computer the plurality of possible influencing agents (pg. 6, lines 23 and 24; pg. 7, lines 24 and 25; and pg. 7, line 29 – pg. 8, line 3);

displaying the plurality of possible influencing agents on the computer display (Fig. 1, item 28 and pg. 7, line 22);

entering the reaction into the computer (pg. 6, lines 23 and 24; pg. 7, lines 20 and 21; and pg. 7, lines 24 and 25);

displaying the reaction on the computer display (Fig. 1 item 30 and pg. 7, lines 23 and 24);

for a first period, selecting a first plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the first plurality of influencing agents during the first period, wherein the step of selecting the first plurality of influencing agents from the plurality of possible influencing agents is performed by mouse-clicking on at least some of the plurality of influencing agents (Fig. 1, item 36 and pg. 7 line 26 – pg. 8 line 7);

for a second period following the first period, selecting a second plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the second plurality of influencing agents during the second period, wherein the step of selecting the second plurality of influencing agents from the plurality of possible influencing agents is performed by mouse-clicking on at least some of the plurality of influencing agents (Fig. 2, item 40 and pg. 8, line 8 – 17);

selecting, via the computer, the reaction that the individual experienced during at least one of the first period, the second period, and a third period, wherein the third period follows the second period (Fig. 2, item 48; Fig. 3, items 58 and 62; and pg. 8, lines 17 – 23);

computing a plurality of correlations corresponding to the plurality of possible influencing agents as each of the plurality of possible influencing agents relate to the reaction (pg. 9, lines 15 – 17; pg. 9, lines 23 – 25; and pg. 10, lines 6 – 10); and

adding, after the first period, an additional influencing agent to the plurality of possible influencing agents (pg. 8, lines 8 – 10).

Independent claim 33 is a combination of claims 1, 3, 4, 5, 9 and 10. More specifically, independent claim 33 finds support in the specification and/or drawings as follows:

33.   A method of using a computer and a computer display for identifying a suspect influencing agent that may be causing a reaction in an individual, the method comprising:

entering into the computer a plurality of possible influencing agents, wherein the plurality of possible influencing agents includes the suspect influencing agent, and wherein at least one of the plurality of possible influencing agents is a food (pg. 6, lines 23 and 24; pg. 7, lines 24 and 25; pg. 7, line 29 – pg. 8, line 3; pg. 7 lines 2 and 3; and pg. 7 lines 28 and 29);

displaying the plurality of possible influencing agents on the computer display (Fig. 1, item 28 and pg. 7, line 22);

entering the reaction into the computer (pg. 6, lines 23 and 24; pg. 7, lines 20 and 21; and pg. 7, lines 24 and 25);

displaying the reaction on the computer display (Fig. 1 item 30 and pg. 7, lines 23 and 24);

for a first period, selecting a first plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the first plurality of influencing agents during the first period, wherein the step of selecting the first plurality of influencing agents from the plurality of possible influencing agents is performed by mouse-clicking on at least some of the plurality of influencing agents (Fig. 1, item 36 and pg. 7 line 26 – pg. 8 line 7);

for a second period following the first period, selecting a second plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the second plurality of influencing agents during the second period, wherein the step of selecting

the second plurality of influencing agents from the plurality of possible influencing agents is performed by mouse-clicking on at least some of the plurality of influencing agents (Fig. 2, item 40 and pg. 8, line 8 – 17);

selecting the reaction that the individual experienced during at least one of the first period, the second period, and a third period, wherein the third period follows the second period, wherein the step of selecting the reaction is performed by mouse-clicking on the reaction (Fig. 2, item 48; Fig. 3, items 58 and 62; and pg. 8, lines 17 – 23);

computing a plurality of correlations corresponding to the plurality of possible influencing agents, wherein the plurality of correlations reflect the likelihood that the plurality of possible influencing agents will cause a future reaction (pg. 9, lines 15 – 17; pg. 9, lines 23 – 25; and pg. 10, lines 6 – 10);

adding, after the first period, an additional influencing agent to the plurality of possible influencing agents (pg. 8, lines 8 – 10);

sorting the plurality of possible influencing agents based on the plurality of correlations (Fig. 4, item 78 and pg. 10, lines 16 and 17);

plotting a graph of the suspect influencing agent and the reaction versus time, and displaying the graph on the computer display to help illustrate how well the suspect influencing agent and the reaction correlate (Fig. 6 and ; and pg. 11, lines 20 – 25); and

assigning a magnitude value to the reaction (Fig. 3, item 66 and pg. 8, line 27 – pg. 9, line 6).

(vi) Grounds of Rejection

5, 5A) Claims 1, 3-4, 7, 12, and 14-29 have been rejected under 35 USC 103(a) as being unpatentable over Verkow et al., THE MERCK MANUAL in view of Evans et al., A COMPUTER ASSISTED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS. Regarding claim 1, the Examiner states that it would have been obvious to one of ordinary skill in the art to include the features of Evans in the method of Berkow with the motivation of providing patient data at the point-of-care.

5B) Regarding Claim 3, the Examiner states that the Evans program is capable of sorting data.

5C) Regarding claim 4, the Examiner states that Berkow discloses the addition of new possible allergens and monitoring for changes in symptoms.

5D) Regarding claim 7, the Examiner states, "Berkow does not explicitly disclose entering additional symptoms; however, Berkow discloses monitoring the recrudescence of symptoms."

5E) Regarding claim 12, the Examiner states that Berkow discloses that the clinical significance of a positive skin test "is determined when results are correlated with the pattern of symptoms and related to environmental exposures."

5F) Regarding claim 14, the Examiner states that Berkow discloses that the influencing agent may be a foodstuff.

5G) Regarding claim 15, the Examiner states that Berkow discloses that ingredients in foods may cause reactions.

5H) Regarding claim 16, the Examiner states that Berkow discloses that symptom occurs some time after the food is ingested.

5I) Regarding claim 17, the Examiner states that Evans discloses determining 95 percent confidence interval.

5J) Regarding claim 18, the Examiner states that Berkow discloses that each period may be one day or more.

5K) Regarding claim 19, the Examiner states that Berkow discloses that "[c]ommonly incriminated food allergens include milk, eggs, shellfish ..."

5L) Regarding claim 20, the Examiner claims that Berkow discloses that the clinical significance is determined when skin test results are correlated with the pattern of symptoms and related to environmental exposures.

5M) Regarding claim 21, the Examiner states that Berkow discloses that "[e]osinophilic enteropthy, which may be related to specific food allergy, is an unusual illness with pain ..."

5N) Regarding claim 22, the Examiner states that Berkow discloses that "[f]ood additives can produce ... asthma"

5O) Regarding claim 23, the Examiner states that Berkow discloses that "perianal eczema have been attributed to food allergy"

5P) Regarding claim 24, the Examiner states that Berkow discloses "[e]osinophilic enteropthy, which may be related to specific food allergy, is an unusual illness with pain... that is associated with blood eosinopilia

5Q) Regarding claim 25, the Examiner states that Berkow discloses that the reaction is suboptimal athletic performance.

5R) Regarding claims 26 and 28, the Examiner states that Berkow discloses that the reaction is depression.

5S) Regarding claim 27, the Examiner states that Berkow discloses that allergy could bring on anaphylaxis, a potentially fatal acute attack.

5T) Regarding claim 29, the Examiner states that Berkow discloses that smoking, i.e., exposure to cigarette smoke, may cause a reaction.

6, 6A) Claims 5, 6, 8 and 32 have been rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERCK MANUAL in view of Evans et al., A COMPUTER ASSISTED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS as applied to Claim 1 and further in view of Rappaport et. al. (4,752,889). As per claim 5, the Examiner states that it would have been obvious to include the

features of Rappaport in the computerized allergy diagnostic system as jointly taught by Berkow and Evans, with the motivation of associating data items for displaying.

6B) Regarding claim 6, the Examiner states that claim 6 repeats the limitations of claim 5 and is therefore rejected for the same reasons.

6C) Regarding claim 8, the Examiner states that Rappaport discloses that chunks may be displayed in the same view to facilitate selection.

6D) Regarding claim 32, the Examiner states that claim 32 repeats the limitations of claims 1 and 4 – 6, cumulatively, and is therefore rejected for the same reasons.

7, 7A) Claim 9 has been rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERK MANUAL in view of Evans et al., A COMPUTER ASSITED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS as applied to Claim 1 above and further in view of Kadtke et al. (6,401,057). The Examiner states that Figure 2B of Kadtke discloses graphing of a correlation parameter versus time delay and that it would have been obvious to generate and display the graph of the correlation versus time delay.

8, 8A, 8B) Claims 10 and 11 have been rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERK MANUAL in view of Evans et al., A COMPUTER ASSITED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS as applied to Claim 1 above and further in view of Small et al. (5,910,421). The Examiner states that Small teaches that magnitude values may be assigned to data points and that it would have been obvious to assign magnitude values to the reaction or to the plurality of influencing agents.

9, 9A) Claim 13 has been rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERK MANUAL in view of Evans et al., A COMPUTER ASSITED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS as applied to Claim 1 above and further in view of Lowy, MEDICAL PROGRESS: STAPHYLOCOCCUS AUREUS INFECTIONS. The Examiner states that it would have been obvious to consider the menstruation cycle, as taught by Lowy, when implementing the automated allergy diagnostic system as jointly taught by Berkow and Evans.

11, 11A) Claim 30 has been rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERK MANUAL in view of Evans et al., A COMPUTER ASSITED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS as applied to Claim 1 above and further in view of Mebane (5,486,999). The Examiner states that it would have been obvious to identify sleep as a possible influencing agent, as taught by Mebane, when implementing the automated allergy diagnostic system as jointly taught by Berkow and Evans.

12, 12A) Claim 31 has been rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERK MANUAL in view of Evans et al., A COMPUTER ASSITED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS as applied to Claim 1 above and further in view of Teller (2002/0013538). The Examiner states that it would have been obvious to correlate patient symptoms with locale-specific environmental data, as taught by Teller, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans.

13, 13A) Claim 33 has been rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERK MANUAL in view of Evans et al., A COMPUTER ASSITED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS, Rappaport et al. (4,752,889), Kadtke et al. (6,401,057), and Small et al. (5,910,421). The Examiner states that Claim 33 repeats the limitations of Claims 1, 3-6, 9, 10, 12 and 14 cumulatively, and is therefore rejected for the same reasons, and incorporated herein.

14, 14A) The Examiner states, "Evans discloses a computer system capable of rudimentary data processing with specific application towards identifying patient allergy."

14B) Regarding claim 1, the Examiner states, "While Applicant's asserted advantages may be true, the scope of the claim also envelops identifying the possible allergens as the results of the skin test, wherein a set of responses is correlated to a set of challenges. Therefore, the asserted advantage is moot with respect to at least some portions of the scope of claim 1.

14C) The Examiner states, "an elimination diet as disclosed by Berkow suggests the method steps of correlating responses to the challenges as recited by Applicant."

14D) The Examiner maintains that "elimination diets fall within the scope of Applicant's claimed invention, and therefore the teachings of Berkow and Evans suggest the limitations of claim 1."

14E) In response to the applicant asserting that Evans does not disclose identifying an unknown allergy, the Examiner states, "one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references." The Examiner maintains that Berkow and Evans in combination jointly teach the limitations of claim 1.

14F) Regarding claim 1, the Examiner further states that "skin testing is a protocol of administering a series of challenges and then observing the test sites for the appropriate response."

14G) As per claim 2, the Examiner states that "the Applicant's argument on page 13 with respect to cancelled claim 2 is found to be not persuasive for the reasons stated above, and incorporated herein.

14H) Regarding claim 3, the Examiner states, "one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references." The Examiner maintains that Berkow and Evans in combination jointly teach the limitations of claim 3.

14I) Examiner cannot attribute any reasonable interpretation to Applicant's argument regarding claim 4 and thus requests additional clarification.

14J) The Examiner states, "Claim 7 recites entering the reaction."

14K) Regarding claim 12, the Examiner maintains that "skin testing is a protocol or correlation challenges with observed responses to determine statistical significance."

14L) Regarding claim 14, the Examiner maintains that "Berkow and Evans jointly disclose a method capable of identifying allergy, including food allergy."

14M) Regarding claim 15, the Examiner maintains that Berkow and Evans jointly disclose a method capable of identifying allergy, including various ingredients contained in food, as discussed above, and incorporated herein. Specifically, Berkow discloses that it is not the

food item itself, but the ingredients contained therein that represent the challenges capable of eliciting a response in the patient.

14N) Regarding claim 16, the Examiner maintains that Berkow discloses the possibility of a time delay between the challenge and the response, as is evident by the symptom occurring some time after ingestion. Examiner further maintains that this disclosure from Berkow in combination of the method as jointly disclosed by Berkow and Evans constitute a "time-delayed" correlation of challenges and responses.

14O) Regarding claim 17, The Examiner states that "Berkow discloses determining statistical significance between challenges as responses, as discussed in the discussion of claim 1 above. Evans discloses that calculating confidence intervals to determine statistical significance is old and well established in the art of statistics. In combination, the cited art suggest the limitations of claim 17."

14P) Regarding claim 18, the Examiner states that Berkow discloses the limitations as recited in claim 18, and that the asserted advantages as argued by Applicant has been suggested by Berkow, as is evident by the fact that multiple diets are prescribed with the goal of identifying the positive challenge.

14Q) Regarding claim 19, the Examiner states that the Applicant did not point out, or was Examiner able to find, any recitation of this limitation (equally numerous allergens) in claim 19.

14R) Regarding claim 20, the Examiner states that "Regardless of the fact that Berkow's method applies to skin test, the challenge administered to the patient represents allergens present as the result of environmental exposure. Correlating the challenge with the fact that the patient has previously experienced the same challenge-response pair creates statistical significance for the allergen in question. Additionally, Berkow also discloses observing responses to food challenges, as discussed in the discussion of claim 1 above."

14S) Regarding claims 21 – 28, the Examiner states, "Applicant admits that the recited allergens are well known to be causes of allergic reactions." The Examiner further states that, "the method as jointly disclosed by Berkow and Evans, and also in combination of the allergens as cited by Examiner and admitted by Applicant, is capable of identifying the recited allergens in claims 21-29."

14T) Regarding claim 29, the Examiner states that the "Applicant argues a newly added limitation not present in the claim as originally presented." The Examiner further states that the "Examiner has changed the ground of rejection as necessitated by Applicant's amendment. It is noted that Examiner maintains that the interpretation adopted by Examiner, and upon which the original rejection was made, is consisted with the claim limitations as originally presented."

14U) Regarding claim 5, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, the Examiner states, "the motivation to combine can be found in Rappaport, which provides a convenient method of selecting displayed data."

14V) Regarding claim 6, the Examiner states that the limitation of claim 6 is substantially the same as the recited in claim 5.

14W) Regarding claim 8, the Examiner states, "Rappaport discloses displaying data in a single view to facilitate selection (Figure 3A-3B). In combination with Berkow and Evans, Rappaport's disclosure anticipates Applicant's claim."

14X) Regarding claim 32, the Examiner states, "claim 32 repeats the limitations of claims 1 and 4-6. Since amended claim 1 is rejected, and since claim 1 incorporates all limitations of cancelled claim 2, it follows that claim 32 is rejected for the same rationale as applied to claims 1 and 4-6, and incorporated herein."

14Y) Regarding claim 9, the Examiner states, "one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In particular, Kadtke's disclosure in combination with Berkow and Evans suggests the claimed invention."

14Z) Regarding claims 10 and 11, the examiner states, "obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation o do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

In this case, the motivation comes from Small to provide a method capable of distinguishing between allergies and infection (Small, col. 6 lines 10-12)."

14AA) Regarding claim 13, the Examiner states, " Applicant argues that the cited art does not recognize the problem where a menstrual period might alter a woman's usually reaction to an influencing agent, nor does the cited art suggest a solution in regards to claim 13. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., selectively considering or disregarding data collected during a menstrual cycle) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Assuming *arguendo* that Applicant is correct that this limitation is present in the claim, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In particular, Berkow discloses that TSS is "almost always associated with menstruation" (page 88 paragraph 5). Lowy discloses tat TSS may be caused by an allergic reaction to insect bit (page 527 column 2 paragraph 2). In combination, the cited art suggest that menstruation affects a patient's response, and if the cause is confounded, the improper treatment arising therefrom may cause patient death (Lowy; page 527 column 2 paragraph 2)."

14AB) Regarding claim 15, the Examiner states, " one cannot show nonobviousness by attacking references individually where rejections are based on combinations of references. In particular, claim 30 recites that the method may operate to identify the amount of sleep of the individual as a possible cause. Mebane discloses that the amount of sleep in a patient is a possible cause of reactions in a patient, and may not warrant clinical treatment. In combination, the cited art disclose the claim limitations."

14AC) Regarding claim 31, the Examiner states that the "Applicant did not specifically point out which limitation of the claim was inadequately addressed by the rejection. Additionally, Applicant's amendment to the claim does not put the claim in condition for allowance for the following reason. The cited art in combination suggest that environmental data may b updated from remote databases to identify the cause of the allergic reaction by correlating the patient's exposure to the information obtained from the databases."

14AD) Regarding claim 33, the Examiner states that the "Applicant does not dispute Examiner's assertion that claim 32 repeats the limitations of claims 1, 3-6, 9, 10 12, and 14. Since amended claim 1 is rejected, and since claim 1 incorporates all limitations of cancelled claim 2, it follows a that claim 33 is rejected for the same rationale as applied to claims 1, 3-6, 9, 10, 12, and 14, and incorporated herein."

(vii) Arguments

Applicants' Position – One-Page Summary

Observing correlations is, of course, nothing new. Using elimination diets, as taught by Berkow, is nothing new. It may seem that computerizing Berkow's elimination diet just to modernize it or make it more efficient, powerful and easier to use is not impressive or patentable. What's being overlooked, however, is that "computerizing" Berkow's method doesn't make it better - **it makes it obsolete!**

With the applicants' invention, there is no need for patients to follow any prescribed elimination diet whatsoever. They can eat whatever they like. Yet the applicants' method can still identify allergens and rank them. If this were such a predictable result, then why would anyone still bother with the trial-and-error method of elimination diets!

How can Berkow's elimination diet be used as the primary basis for rejecting an invention intended to avoid and eliminate such a prescribed diet! (see Abstract)

The above argument alone does not point out specific elements in the applicants' claims that are not found in the prior art; however, the novelty aspect of the claims in not in question, as the claims are rejected under 35 USC 103, not 35 USC 102. The above argument, however, does establish the nonobviousness of the invention. Even the recent decision of KSR International vs. Teleflex preserves the patentablity of an invention that is nonobvious for providing an unpredictable result. In the applicants' case, the surprising, unexpected result is being able to entirely eliminate the need for a prescribed elimination diet, plus being able to identify allergens while using a patient's normal routine diet. None of the cited art suggests such a result.

In addition to the preceding argument, the applicants feel obligated to address some additional points mentioned in the Examiner's Answer mailed March 20, 2008.

(vii) Arguments (continued)

Additional Arguments

In the Final Rejection mailed May 4, 2007, the Examiner has organized the rejections, reasons and comments by way of sections labeled 5, 5A – 5T, 6, 6A – 6D, 7, 7A, 8, 8A – 8B, 9, 9A, 11, 11A, 12, 12A, 13, 13A, 14, 14A – 14Z, and 14AA – 14AD, so the applicants tried to follow that same format in responding to each point of rejection in the original appeal brief mailed on September 25, 2007, and the applicants continue to stand by the arguments therein. However, in the Examiner's Answer mailed March 20, 2008, the Examiner seems to have selected some of the Applicant's arguments (while disregarding others) and listed the selected ones along with the Examiner's corresponding answers by way of sections now labeled A – Z. In the Examiner's Answer, it appears that the new sections A – Z may not directly address some of applicants' arguments in the Appeal Brief, namely sections 5F, 5G, 5L, 5M, 5N, 5O, 5P, 5Q, 5R, 5S, 6D, 13, 13A, 14D, 14E, 14G- Z, 14AA-14AD. The Examiner's Answer does not appear to address the applicant's arguments regarding independent claims 32 and 33. The Applicants found the Examiner's original outline (5, 5A-5T, 6, … 14AD) somewhat confusing, and now shifting midstream to a different outline (A-Z) adds to the confusion. Nonetheless, the applicants will try to follow the Examiner's new format as much as possible.

When listing how the Berkow elements supposedly match those of the applicants' claim 1, the Berkow list in the final rejection (pgs. 3 and 4) is different than the list in the Examiner's Answer (pg. 5). The changes are relevant, particularly element (e), yet the Examiner has not provided any reason for having made the changes. In the final rejection, the Examiner says that Berkow <u>calculates</u> the correlation between symptoms and exposures to possible allergens. Berkow, however, does not appear to <u>calculate</u> any correlation – besides, a correlation "between symptoms and exposures to possible allergens," as stated by the Examiner, isn't very clear, i.e., what is a correlation of three items: symptoms, exposures, possible allergens. The applicants do not understand the Examiner's "three-element correlation" statement, thus the applicants are unable to address the Examiner's point.

In the Examiner's Answer mailed March 20, 2008, the Examiner says that Berkow determines the relationship between food and symptoms. An important element of the applicants' invention, however, is the step of computing a correlation. It is this seemingly insignificant step that helps render Berkow's elimination diet obsolete.

On pg. 6 of the Examiner's Answer, the Examiner states that Evans teaches "...the computer automatically checks for allergies" With the Evans system someone needs to input a known allergy into the computer.

On pg. 6 of the Examiner's Answer, the Examiner states "Berkow further teaches confirming positive challenges (reads on 'sorting')" which seems to contradict what the Examiner states on pg. 5 of the Final Rejection, specifically, "Berkow does not explicitly disclose that the correlation is sorted"

On pg. 8 of the Examiner's Answer and in reference to claim 17, the Examiner states, "Berkow teaches establishing clinical significance for a positive skin prick test (page 650 paragraph 4). The applicants understand this as simply meaning an elimination diet is used to confirm test results of a skin prick test. However, the applicants' claim 17 recites assigning a confidence value to the computed correlation. The applicants' invention does not use an elimination diet.

On pg. 9 of the Examiner's Answer, the Examiner references claim 20; however, the Examiner's comments do not seem to relate to applicants' claim 20 whatsoever. It appears that this paragraph is a typographical error.

On pg. 13 – 14 of the Examiner's Answer and in reference to claim 13, the Examiner says that Lowy teaches that TSS may be caused by an allergic reaction to an insect bite. That's not true. Lowy makes no mention of any allergen as being a cause of TSS. Lowy says that TSS can be associated with enterotoxins (toxin produced by microorganisms) – localized infection, surgery, insect bites. The Examiner also points out that Berkow teaches that TSS is almost always associated with menstruation. The Examiner concludes that it would be obvious to combine the teachings under the motivation of accurately diagnosing the cause of TSS. Even though the cited art teaches that TSS can be caused by various sources, the cited art fails to

suggest a way of identifying the source. Claim 13, however, specifically recites selectively using a first and second computation of correlation, wherein the two computations are differentiated.

Regarding independent claim 32, in the Final Rejection the Examiner states that Claim 32 repeats the limitations of Claims 1 and 4 – 6, cumulatively, and is therefore rejected for the same reasons. Claim 32, however, also includes the limitations of original Claim 2. Thus, applicant submits that Claim 32 should be allowed for reasons presented with reference to Claims 1, 2, and 4 – 6. The applicants stand by their argument presented in section 14X of the Appeal Brief.

Regarding independent claim 33, in the Final Rejection the Examiner states that Claim 33 repeats the limitations of Claims 1, 3-6, 9, 10, 12 and 14, cumulatively, and is therefore rejected for the same reasons. Claim 33, however, also includes the limitations of original Claim 2. Thus, applicant submits that Claim 33 should be allowed for reasons already presented with reference to Claims 1-6, 9, 10, 12 and 14.

Section A) The Examiner never addresses the applicants' argument (5, 5A of Appeal Brief) that in Berkow the **test results and the symptoms** are compared for correlation, but with the applicants' invention, the **exposures and the symptoms** are compared for correlation.

On pg. 650, paragraph 4, Berkow states, "results are correlated with the pattern of symptoms and related to environmental exposures." Berkow's statement is a little confusing, but it appears that Berkow is saying that the results are correlated with the pattern of symptoms, and the results are related to environmental exposures. The applicant is having difficulty making sense of this, but the fact that Berklow clearly states "the results are correlated with the pattern of symptoms" appears to mean the **test results and the symptoms** are compared for correlation, whereas in the case of the applicant's invention, the **exposures and the symptoms** are compared for correlation. It appears that Berkow compares the **test results** of the skin prick test to the **symptoms** of the elimination diet as a way of validating the results of the skin prick test (Berkow, pg. 650, paragraph 4, last sentence).

Section B) The applicants' invention does not require the use of a skin prick test or an elimination diet.

Section C) The Examiner submits that embodiments comprising manually computing a correlation and entering that into a computer is enveloped by claim 1. The cited art, however, even fails to disclose manually computing a correlation and entering the computed correlation into a computer.

Section D) It appears to the applicants that the cited art fails to quantify various levels of exposure/symptom correlations, thus the cited art fails to provide any means for sorting such data.

Section E) The applicants stand by their argument presented in section 5B of the Appeal Brief.

Section F)   The applicants stand by their argument presented in section 5C of the Appeal Brief.

Section G) The applicants stand by their argument presented in section 5D of the Appeal Brief, plus the Examiner has not pointed out where the cited art suggests entering a plurality of reactions into a computer.

Section H) The applicants stand by their argument presented in section 5E of the Appeal Brief.

Section I) The applicants stand by their argument presented in section 5H of the Appeal Brief.

Section J) The Examiner mentions that the applicants specification states, "In some cases, a confidence value 74 may be assigned to a correlation value..." The Examiner questions the phrase, "In some cases." That merely means, "in some embodiments," and claim 17 would cover those embodiments. The Examiner states the Berkow teaches, "clinical significance is a measure of how reliable the positive result is, and should be correlated with patterns of symptoms and related to environmental exposures (page 650 paragraph 4)." Isn't that saying that clinical significance should be correlated with patterns of symptoms? That doesn't make sense. The applicants stand by their argument presented in section 5I of the Appeal Brief.

Section K) The applicants stand by their argument presented in section 5J of the Appeal Brief.

Section L) The applicants stand by their argument presented in section 5K of the Appeal Brief.

Section M) The applicants stand by their argument presented in section 5T of the Appeal Brief.

Section N) The Examiner submits that KSR International vs. Tleflex (KSR) forecloses the argument that a specific teaching, suggestion or motivation (TSM) is required to support a finding of obviousness. The applicants, however, point out that the decision of KSR does not say that TSM is completely irrelevant. Without some teaching, suggestion or motivation mentioned in the prior art, the Examiner still needs to present some reasonable rational for determining that the applicants' invention is obvious. Moreover, KSR preserves the patentability of an invention that is nonobvious for providing an unpredictable result. In the applicants' case, the surprising,

unexpected result is being able to entirely eliminate the need for a prescribed elimination diet, plus being able to use a patient's normal routine diet to identify allergens.

Section O) The applicants stand by their argument presented in section 6O of the Appeal Brief.

Section P) In response to the Examiner saying that the applicants have not argued any particular limitation per se was not known in the art, the applicants point out that claim 8 recites only one method step, and that step is not found in the cited art, separately or combined. The applicants also stand by their argument presented in section 6C of the Appeal Brief.

Section Q) The Examiner says that the applicants argument relies on the invention having a 3-dimensional graph comprising the suspect influencing agent, the reaction and a timescale, and that is not recited in claim 9. Actually, the applicants have neither argued nor claimed a 3-dimensional graph. Claim 9, however, does specifically recite "plotting a graph of the suspect influencing agent and the reaction versus time,' and the Examiner has not pointed out where the prior art discloses that particular relationship. Kadtke discloses a graph showing a correlation parameter vs. a time delay, but that is not what the applicants are claiming. Claim 9 recites a plot of an influencing agent and a reaction, not some correlation parameter. The applicants also stand by their argument presented in sections 7,7A of the Appeal Brief.

Section R) Applicant believe Figure 2 of Small illustrates the number of patients, not a score or magnitude to a reaction, and Figure 1 appears to the applicants as an illustration of whether or not something exists, not its magnitude. The applicants stand by their argument presented in section 8/8A of the Appeal Brief.

Section S) The applicants stand by their argument presented in section 8/8B of the Appeal Brief.

Section T) The Examiner argues that "nowhere in any claim does the Appellant recite considering or disregarding menstrual data." The applicants agree to a certain extent. However, more importantly, claim 13 does recite, "the correlation is based selectively on a first computation and a second computation, which are differentiated by how the first computation and the second computation account for a menstrual period." With that specific language, claim 13 covers (i.e., encompasses, envelopes, reads upon, etc.) the extremely narrow concept of selectively considering or disregarding data collected during a menstrual cycle.

The Examiner states that "Appellant has not claimed that the two computations are actually different, only that this basis may be used to differentiate the computations." Claim 13, however, specifically states that the two computations are differentiated, and the Merriam-Webster online dictionary defines differentiate as follows: 1 : to obtain the mathematical derivative of 2 : to mark or show a **difference** in : constitute a **difference** that distinguishes 3 : to develop **differential** characteristics in 4 : to cause **differentiation** of in the course of development 5 : to express the specific distinguishing quality of : DISCRIMINATE *intransitive verb* 1 : to recognize or give expression to a **difference** 2 : to become distinct or **different** in character 3 : to undergo **differentiation.** The applicants submit that the correlation is based selectively on two different computations.

Examiner also says that Lowy teaches that TSS may be caused by an allergic reaction to an insect bite. That's not true. Lowy makes no mention of any allergen as being a cause of TSS. Lowy says that TSS can be associated with enterotoxins (toxin produced by microorganisms) – localized infection, surgery, insect bites. The Examiner also points out that Berkow teaches that TSS is almost always associated with menstruation. The Examiner concludes that it would be obvious to combine the teachings under the motivation of accurately diagnosing the cause of TSS. Even though the cited art teaches that TSS can be caused by various sources, the cited art fails to suggest a way of identifying the source. Claim 13, however, specifically recites selectively using a first and second computation of correlation, wherein the two computations are differentiated.

The applicants stand by their argument presented in section 9,9A of the Appeal Brief.

Section U) The applicants stand by their argument presented in section 11,11A of the Appeal Brief.

Section V) The applicants stand by their argument presented in section 12,12A of the Appeal Brief. Claim 31 specifically recites, downloading into the computer Internet accessible data that relates to an environmental exposure, and computing a second correlation between the environmental exposure and the reaction. The cited art fails to disclose this element of the applicants' invention.

Section W) The Examiner states that Evans teaches that the system is capable of addressing patient allergies. It appears, however, that allergy data is simply entered into the computer system of Evans, which then makes the data available for viewing. The applicants stand by their argument presented in section 14,14A of the Appeal Brief.

Section X) The applicants stand by their argument presented in section 14B of the Appeal Brief.

Section Y) If the Examiner is correct about Berkow suggesting a patient eliminate several foods to eliminate the reaction and then reintroduce the foods one at a time to discover which one is causing the problem, then the Berkow elimination diet may never determine the allergen for a couple of reasons. One, you might never find a set of foods that when avoided as a group eliminate the reaction. Two, in some cases, a reaction might only occur when the patient is exposed to a plurality of mildly allergenic foods, so if those mild allergens are reintroduced one at a time, a reaction might only occur when the third food is added. The applicants' invention as claimed avoids both of these problems. The applicants stand by their arguments presented in section 14C, 14D, and 14E of the Appeal Brief.

Section Z) The applicants stand by their argument presented in section 14C, 14D, 14E and 14Fof the Appeal Brief.

Statements made by the Examiner in the Final Rejection but omitted in the Examiner's Answer, include the following:

- Berkow does not explicitly disclose the use of a computer to automate the method (pg. 4)

- Berkow does not explicitly disclose that the correlation is sorted (pg. 5)

- Berkow does not explicitly disclose entering additional symptoms (pg. 5)

- Berkow does not disclose assigning a confidence value to the correlation (pg. 7)

(viii) Claims Appendix

1.   A method of using a computer and a computer display for identifying a suspect influencing agent that may be causing a reaction in an individual, wherein the suspect influencing agent is one of a plurality of possible influencing agents, the method comprising:

displaying the plurality of possible influencing agents on the computer display;

displaying the reaction on the computer display;

for a first period, selecting a first plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the first plurality of influencing agents during the first period, wherein the step of selecting the first plurality of influencing agents is via the computer;

for a second period following the first period, selecting a second plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the second plurality of influencing agents during the second period, wherein the step of selecting the second plurality of influencing agents is via the computer;

selecting, via the computer, the reaction that the individual experienced during at least one of the first period, the second period, and a third period, wherein the third period follows the second period;

computing a plurality of correlations corresponding to the plurality of possible influencing agents as each of the plurality of possible influencing agents relate to the reaction; and

based on the plurality of correlations, determining and displaying the suspect influencing agent.

3.   The method of claim 1, further comprising sorting the plurality of possible influencing agents based on the plurality of correlations.

4.   The method of claim 1, further comprising adding, after the first period, an additional possible influencing agent to the plurality of possible influencing agents.

5.   The method of claim 1, wherein the step of selecting the first plurality of influencing agents from the plurality of possible influencing agents is performed by mouse-clicking on at least some of the plurality of possible influencing agents.

6.   The method of claim 1, wherein the step of selecting the reaction that the individual experienced involves mouse-clicking on the reaction.

7.   The method of claim 1, further comprising entering a plurality of reactions into the computer wherein the plurality of reactions includes the reaction.

8.   The method of claim 1, further comprising displaying a single view of the reaction and the plurality of possible influencing agents on the computer display, wherein the single view assists in selecting the reaction and assists in selecting the first plurality of influencing agents.

9.   The method of claim 1, further comprising plotting a graph of the suspect influencing agent and the reaction versus time, and displaying the graph on the computer display to help illustrate how well the suspect influencing agent and the reaction correlate.

10.   The method of claim 1, further comprising assigning a magnitude value to the reaction.

11.   The method of claim 1, further comprising assigning a magnitude value to each of the first plurality of influencing agents.

12.   The method of claim 1, wherein the plurality of correlations includes a correlation that reflects the likelihood that the suspect influencing agent may cause a future reaction.

13.   The method of claim 1, wherein the plurality of correlations are based selectively on a first computation and a second computation, the first computation and the second computation are differentiated from each other by how the first computation and the second computation account for a menstrual period.

14.   The method of claim 1, wherein at least one of the plurality of possible influencing agents is a food.

15.   The method of claim 14, further comprising specifying an ingredient for the food, and computing a correlation between the ingredient and the reaction.

16.   The method of claim 1, further comprising computing a time-delayed correlation between the suspect influencing agent and the reaction.

17.   The method of claim 1, further comprising assigning a plurality of confidence values to the plurality of correlations.

18.   The method of claim 1, wherein the first period and the second period are sequential days.

19.   The method of claim 1, wherein the suspect influencing agent is an allergen.

20.   The method of claim 1, wherein the suspect influencing agent is an environmental exposure.

21.   The method of claim 1, wherein the reaction is a physical pain.

22.   The method of claim 1, wherein the reaction is respiratory-related.

23.   The method of claim 1, wherein the reaction is skin-related.

24.   The method of claim 1, wherein the reaction is blood pressure.

25.   The method of claim 1, wherein the reaction is fatigue.

26.   The method of claim 1, wherein the reaction is mentally-related.

27.   The method of claim 1, wherein the reaction is a seizure.

28.   The method of claim 1, wherein the reaction is an emotional disturbance.

29.   The method of claim 1, wherein the suspect influencing agent is an activity of the individual.

30.   The method of claim 1, wherein the suspect influencing agent relates to an amount of sleep of the individual.

31.   The method of claim 1, further comprising downloading into the computer Internet accessible data that relates to an environmental exposure, and computing a correlation between the environmental exposure and the reaction, wherein the step of determining and displaying the suspect influencing agent is further based on the correlation between the environmental exposure and the reaction.

32.   A method of using a computer and a computer display for identifying a suspect influencing agent that may be causing a reaction in an individual, wherein the suspect influencing agent is one of a plurality of possible influencing agents, the method comprising:

      entering into the computer the plurality of possible influencing agents;

      displaying the plurality of possible influencing agents on the computer display;

      entering the reaction into the computer;

      displaying the reaction on the computer display;

for a first period, selecting a first plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the first plurality of influencing agents during the first period, wherein the step of selecting the first plurality of influencing agents from the plurality of possible influencing agents is performed by mouse-clicking on at least some of the plurality of possible influencing agents;

for a second period following the first period, selecting a second plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the second plurality of influencing agents during the second period, wherein the step of selecting the second plurality of influencing agents from the plurality of possible influencing agents is performed by mouse-clicking on at least some of the plurality of influencing agents;

selecting, via the computer, the reaction that the individual experienced during at least one of the first period, the second period, and a third period, wherein the third period follows the second period;

computing a plurality of correlations corresponding to the plurality of possible influencing agents as each of the plurality of possible influencing agents relate to the reaction;

adding, after the first period, an additional influencing agent to the plurality of possible influencing agents; and

based on the plurality of correlations, determining and displaying the suspect influencing agent.

33. A method of using a computer and a computer display for identifying a suspect influencing agent that may be causing a reaction in an individual, the method comprising:

entering into the computer a plurality of possible influencing agents, wherein the plurality of possible influencing agents includes the suspect influencing agent, and wherein at least one of the plurality of possible influencing agents is a food;

displaying the plurality of possible influencing agents on the computer display;

entering the reaction into the computer;

displaying the reaction on the computer display;

for a first period, selecting a first plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the first plurality of

influencing agents during the first period, wherein the step of selecting the first plurality of influencing agents from the plurality of possible influencing agents is performed by mouse-clicking on at least some of the plurality of possible influencing agents;

for a second period following the first period, selecting a second plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the second plurality of influencing agents during the second period, wherein the step of selecting the second plurality of influencing agents from the plurality of possible influencing agents is performed by mouse-clicking on at least some of the plurality of possible influencing agents;

selecting the reaction that the individual experienced during at least one of the first period, the second period, and a third period, wherein the third period follows the second period, wherein the step of selecting the reaction is performed by mouse-clicking on the reaction;

computing a plurality of correlations corresponding to the plurality of possible influencing agents, wherein the plurality of correlations reflect the likelihood that the plurality of possible influencing agents will cause a future reaction;

adding, after the first period, an additional influencing agent to the plurality of possible influencing agents;

sorting the plurality of possible influencing agents based on the plurality of correlations;

plotting a graph of the suspect influencing agent and the reaction versus time, and displaying the graph on the computer display to help illustrate how well the suspect influencing agent and the reaction correlate;

assigning a magnitude value to the reaction; and

displaying the magnitude value on the computer display.

(ix) Evidence Appendix

None

(x) Related Proceedings Appendix

None

Respectfully submitted,

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